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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,641

03/28/2008

Yousef Al-Abed

50425/262

1663

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7590

06/29/2010

AMSTER, ROTHSTEIN & EBENSTEIN LLP
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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

06/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,641	Applicant(s) AL-ABED, YOUSEF	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,10,11 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,11,27 and 28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/10</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. Applicant's amendment, remarks, and IDS, filed 4/15/10, are acknowledged.

2. Claims 10 and 26 stand withdrawn from further consideration by the examiner under 37 CFR 1.142(b), as being drawn to a non-elected species (an Fab or F(ab)₂ fragment does not comprise a whole antibody).

Claims 1, 3, 11, 27, and 28 are under examination.

3. The amended Title and Abstract have been entered.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 11, 27, and 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/64749 (IDS).

As set forth previously, WO 01/64749 teaches the treatment of diabetes (diabetic retinopathy) comprising administering to a human an antibody that inhibits MIF (see particularly page 32 and Claim 53). Said antibodies include monoclonal and humanized antibodies (see particularly pages 9 and 10).

The reference clearly anticipates the claimed invention.

Applicant's arguments, filed 4/15/10, have been fully considered but are not found persuasive. Applicant argues that the reference does not teach the inhibition of type 1 diabetes.

The reference teaches the treatment of diabetic retinopathy, the most readily envisaged would be diabetic retinopathy associated with type 1 diabetes. Retinopathy associated with type 1 diabetes would be the most readily envisaged because the condition is associated with long-term disturbances in the blood glucose level and since type 1 diabetes generally presents during childhood or adolescence it is a condition often seen in type 1 diabetics as they age. Accordingly, the reference anticipates the claimed method.

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3, 11, 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bojunga et al. (2003, IDS) in view of Nishihira and Ogata (2001, Abstract).

As set forth previously, Bojunga et al. teaches the treatment of diabetes comprising the administration of a MIF inhibitor (see particularly page 185).

The reference teaching differs from the claimed invention in that it does not teach an antibody MIF inhibitor nor the treatment of human diabetes.

Nishihira and Ogata teach that an anti-MIF antibody and a small organic molecule are interchangeable in the context of therapeutic *in vivo* treatments (see particularly the Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to treat diabetes, as taught by Bojunga et al., with an anti-MIF antibody because Nishihira and Ogata teach that small organic molecules are interchangeable with antibodies in the context of therapeutic *in vivo* treatments. The choice of either for the treatment of diabetes would not render the method patentably distinct. Regarding the treatment of humans, given that humans are the major sufferers of diabetes, the treatment of humans would be obvious.

Applicant's arguments, filed 4/15/10, have been fully considered but are not found persuasive. Applicant argues that in the primary reference, Bojunga et al., MIF protein levels in the diabetic animals were less than in normal controls. Applicant admits the reference teaches that MIF treatment led to an increase of diabetes, but argues that it was statistically insignificant.

Regarding MIF protein levels, the reference teaches that lymphocytic MIF levels were reduced in diabetic animals likely because of protein secretion. Regarding the increased diabetes in MIF-treated animals, the authors taught that while the increase may not have been significant (86% diseased in MIF-

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treated versus 55% diseased absent MIF treatment) a trend was noted.

Applicant argues that the reference does not provide data supporting the claimed method.

Had the authors of the reference actually performed the specific method of the claims the rejection would have been under 35 U.S.C. 102 and not 35 U.S.C. 103(a). The conclusion that anti-MIF therapies might serve to treat type 1 diabetes combined with the secondary reference, Nishihira and Ogata, teaching an anti-MIF antibody for use in anti-MIF treatments, renders the method of the instant claims obvious.

8. Claim 28 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bojunga et al. (2003, IDS) in view of Nishihira and Ogata (2001), as applied to Claims 1, 3, 11, 27 above, in further view of U.. Patent No. 5,530,101.

As set forth previously, Bojunga et al. and Nishihira and Ogata have been discussed above.

The method of the combined references differs only from the claimed method in that it does not employ a humanized monoclonal antibody. The '101 patent, however, teaches that humanized antibodies are preferred for the treatment of humans because they are less immunogenic to humans (see particularly the Abstract). Thus, the use of a humanized anti-MIF antibody would be preferred and obvious for the treatment of human diabetes.

Applicant's arguments, filed 4/15/10, have been fully considered but are not found persuasive. Applicant does not argue this rejection separately; Applicant reiterates the argument traversing the rejection of the claims in view of Bojunga et al. and Nishihira and Ogata.

See the Examiner's response in section 7, above.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

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is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0841.

12. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
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